REMARKS

Prior to the present amendment, claims 15, 16, 21-23, and 38-42 were pending. By this amendment, applicants have amended claims 15, 38, 39, and 42, and cancelled claim 40. Accordingly, claims 15, 16, 21-23, 38, 39, and 41-42 are currently pending.

In the office action, the examiner has withdrawn the U.S.C. 103(a) rejection of claim 15 over Wands raised in the office action dated January 5, 2006. Applicants appreciate the examiner's consideration and cooperation in making progress with the case.

Rejection under 35 U.S.C. 102 over Tabor et al. in light of Bowen et al.

On page 2 of the office action, claims 15, 16 and 21-23 were rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Tabor et al. (U.S. Patent No. 4,547,368) in light of Bowen et al. (*Research Virology*, 1992, 143:269-278, abstract only). The examiner alleges that Tabor et al. teaches a combination vaccine formulation comprising a mixture of 20 μg of HBsAg and 50 μg of Hepatitis B nucleocapsid.

Applicants respectfully disagree. Merely in order to expedite prosecution, applicants have amended the claims so that they are now limited to a vaccine formulation containing (i) HBsAg and (ii) a viral nucleocapsid. It is well known to those skilled in the art that the term "nucleocapsid" refers to nucleic acids and surrounding protein coat of a virus. An example of a nucleocapsid useful in the claimed invention is HBcAg.

In stark contrast to the claimed invention, Tabor et al. discloses the use of a vaccine formulation containing HBsAg and HBcAg. Contrary to the examiner's assertion, the HBcAg useful in Tabor et al. is not a nucleocapsid. See for example, column 1, lines 58-62, which discloses the use of "a recombinant HBcAg vaccine ... antigen without any nucleic acid ...." (see column 1, lines 58-62). Therefore, Tabor et al. teaches away from the use of HBcAg nucleocapsid. Bowen et al. teaches subcutaneous

and nasal delivery of herpes simplex virus vaccine. Bowen et al. also does not disclose or suggest a vaccine containing HBsAg and a viral nucleocapsid.

Accordingly, Tabor et al. in light of Bowen et al. does not disclose or suggest a vaccine formulation containing HBsAg and a viral nucleocapsid, as is required in the claimed invention.

Accordingly, the claimed invention is not anticipated by the cited references. Therefore, applicants respectfully request that the rejection of the claims under 35 U.S.C. 102(b) be reconsidered and withdrawn.

Rejection under 35 U.S.C. 103(a) over Tabor et al. in light of Bowen et al. and further in view of Rose et al. and Hauser et al.

On page 3 of the office action, claims 38-41 were rejected under 103(a) for allegedly being obvious over Tabor et al. in light of Bowen et al. and further in view of Rose et al. and Hauser et al.

Applicants respectfully disagree. Tabor et al. discloses a vaccine containing HBsAg and HBcAg without nucleic acids for subcutaneous administration. Bowen et al. teaches subcutaneous and nasal delivery of herpes simplex virus vaccine. Rose et al. discloses the administration of HPV VLPs. Hauser et al. discloses vaccine compositions that are administered intramuscularly.

Merely in order to expedite prosecution, applicants are amended the claims so that they are now limited to a vaccine formulation for mucosal administration containing (i) HBsAg and (ii) a second vaccine antigen and a third vaccine antigen, wherein the second or third vaccine antigen is a viral nucleocapsid.

As stated above in the 102(b) rejection, the primary references cited by the examiner, namely Tabor et al. in light of Bowen et al., do not disclose or suggest a formulation containing (i) HBsAg and (ii) a viral nucleocapsid. The secondary references cited by the examiner, specifically, Rose et al. and Hauser et al. also do not disclose or suggest a formulation containing HBsAg and a viral nucleocapsid. Without such a disclosure, the claimed invention cannot be obvious over the cited references.

Accordingly, applicants respectfully request that the rejection of the claims under 35 U.S.C. 103(a) over Tabor et al. in light of Bowen et al. and further in view of Rose et al. and Hauser et al. be reconsidered and withdrawn.

Rejection under 35 U.S.C. 103(a) over Tabor et al. in view of McCluskie et al.

On page 4 of the office action, claim 42 was rejected under 35 U.S.C. 103(a) for allegedly being obvious over Tabor et al. in view of McCluskie et al.

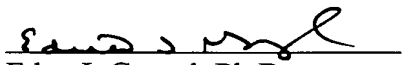
Applicants respectfully disagree. Merely in order to expedite prosecution, applicants are amended the claims so that they are now limited to mucosal administration of a vaccine formulation containing (i) HBsAg and (ii) a viral nucleocapsid. As stated above in the 102(b) rejection, Tabor et al. does not disclose or suggest a formulation containing (i) HBsAg and (ii) a viral nucleocapsid.

MuCluskie et al. also does not disclose or suggest mucosal administration of a vaccine formulation containing HBsAg and a viral nucleocapsid. Without such a disclosure, the claimed invention cannot be obvious over the Tabor et al. in view of McCluskie et al.

Accordingly, applicants respectfully request that the rejection of claim 42 over Tabor et al. in view of McCluskie et la. be reconsidered and withdrawn.

For the above reasons, allowance of the pending claims is earnestly requested. If the examiner has any questions or concerns regarding this matter, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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